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INSTRUMENTS AND METHODS FOR ALIGNING IMPLANTS FOR INSERTION

Cross-Reference to Related Applications

[0001] This application claims the benefit of U.S. Provisional Application No. 60/446,963 filed on February 12, 2003. U.S. Provisional Application No. 60/446,963 is herein incorporated by reference for all legitimate purposes. This application is also related to U.S. Patent Application Serial No. 10/430,473, which is herein incorporated by reference for all legitimate purposes.

Background

[0002] The present disclosure relates generally to the field of orthopedics and spinal surgery, and in some embodiments, the present disclosure relates to instrumentation and methods for the insertion of prosthetic devices.

[0003] In the treatment of diseases, injuries or malformations affecting spinal motion segments, and especially those affecting disc tissue, it has long been known to remove some or all of a degenerated, ruptured or otherwise failing disc. In cases involving intervertebral disc tissue that has been removed or is otherwise absent from a spinal motion segment, corrective measures are taken to ensure the proper spacing of the vertebrae formerly separated by the removed disc tissue. In some instances, prosthetic devices are inserted into the disc space to maintain the structural integrity of the spinal column.

[0004] Implantation of prosthetic devices and associated tools and instrumentation has heretofore been accomplished with the aid of complex electronic equipment such as intraoperative X-ray (Fluoroscopy) equipment. However, the use of such equipment can bear burdensome costs while the complexity of the equipment complicates the procedures associated with the use of the equipment. Alternatives to the use of complex electronic

equipment during the insertion of prosthetic devices into the human body are therefore desirable.

[0005] Therefore, what is needed is are instrumentation and methods for aligning implants for insertion, which reduce, or eliminate, the use of fluoroscopic equipment.

Summary

[0006] An instrument for aiding in aligning a prosthetic device for insertion into an intervertebral space is described. The instrument includes an annular housing, a plunger member disposed within the annular housing and adapted to be moved therethrough, and an anchoring device partially disposed within the annular housing, the anchoring device adapted to be driven by the plunger member.

[0007] An assembly for aligning a prosthetic device for insertion into an intervertebral space is provided. The assembly includes means for anchoring an alignment instrument in a vertebral body disposed adjacent to the intervertebral space, means for operatively connecting an implantation device to the alignment instrument, the prosthetic device being disposed on the implantation device, and means for adjusting the implantation device to position the prosthetic device adjacent to the intervertebral space.

[0008] An assembly for aligning a prosthetic device for insertion into an intervertebral space is provided. The assembly includes an alignment instrument, a first clamp assembly slidably engaged with the alignment instrument, a second clamp assembly slidably engaged with the first clamp assembly, and an implantation device slidably engaged with the second clamp assembly, the implantation device being adapted to retain a prosthetic device thereon.

[0009] A method for aligning a prosthetic device for insertion into an intervertebral space is described. The method includes providing an alignment instrument having an anchoring device extending therefrom, engaging the anchoring device with a vertebral body located adjacent to the intervertebral space, aligning the alignment instrument relative to the intervertebral space, driving the anchoring device into the vertebral body, and providing an implantation device adjacent to the alignment instrument via a clamp assembly operatively connected to the alignment instrument, the implantation device holding the prosthetic device at a distal end thereof.

Brief Description of the Drawings

[0010] Fig. 1 is an anterior view of an intervertebral space defined between a pair of vertebral bodies.

[0011] Fig. 2 is a perspective view of an assembly incorporating an alignment instrument and an implantation device according to one embodiment of the present disclosure.

[0012] Fig. 3A is a sectional view of the alignment instrument of Fig. 2.

[0013] Fig. 3B is a detailed view of a portion of the alignment instrument of Fig. 3A.

[0014] Fig. 4 is a perspective view of the assembly of Fig. 2 shown schematically in use during implantation of a prosthetic device.

[0015] Fig. 5 is an exploded view of an alternative alignment instrument according to another embodiment of the present disclosure.

Description

[0016] This disclosure relates generally to instrumentation and methods for delivering prosthetic devices under mechanical guidance and, in some instances, providing limited fluoroscopic guidance to aid in such mechanical guidance. For the purposes of promoting an understanding of the principles of the disclosure, reference will now be made to the embodiments, or examples, illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the disclosure is thereby intended. Any alterations and further modifications in the described embodiments, and any further applications of the principles of the disclosure as described herein are contemplated as would normally occur to one skilled in the art to which this disclosure relates. As such, individual features of separately described embodiments can be combined to form additional embodiments.

[0017] Referring now to Fig. 1, shown therein is an anterior view of a portion of a spinal column 10, illustrating a pair of adjacent upper and lower vertebrae V1 and V2 separated by an intervertebral space S created by the removal of a natural intervertebral disc. The illustration of two vertebrae is only intended as an example. Another example would be a sacrum and one vertebrae.

[0018] Referring now to Figs. 2, 3A and 3B, an assembly for aiding in the implantation of a prosthetic device into the intervertebral space S (Fig. 1) is generally referred to by reference numeral 20, and is shown, in one embodiment, as including an alignment instrument 22 and an associated implantation device 24. It is understood that the alignment instrument 22 may

be used to aid in the implantation of a variety of prosthetic devices such as screws, cages, total joint implants, etc. In one embodiment, the alignment instrument 22 is generally linear in shape and extends along an X-axis defined by the longitudinal axis of the alignment instrument. The alignment instrument 22 includes a plunger member 26 positioned within a generally annular housing 28 of the instrument, and a knob 30 integrally formed with the proximal end of the plunger member 26. In this manner, rotation of the knob 30 is adapted to impart rotation to the plunger member 26. An anchoring device, such as a threaded bone screw 32, is disposed within the distal end of the alignment instrument 22 to receive a rotational and a translational force from the plunger member 26 as will be further described. In one embodiment, the bone screw 32 is formed of a radiopaque material such as steel. In the present disclosure, the term "proximal" refers to the direction generally towards a user, such as a surgeon (not shown), of the alignment instrument 20, and the term "distal" refers to the direction generally towards a patient (not shown).

[0019] In one embodiment, an inner annular surface 34 of the housing 28 includes a threaded portion 36 for receiving and engaging a corresponding threaded portion 38 of the plunger member 26. Accordingly, rotation of the plunger member 26 via the knob 30, not only rotates the plunger member in the housing, but translates the plunger member through the housing 24 as well. As better seen in Fig. 3B, the distal end of the plunger member 26 includes a spherical-shaped groove 40 formed therein, which is adapted to engage a spherical head 42 of the bone screw 32. In the present example, the distal end of the housing 28 is reduced in diameter and chamfered to allow a threaded portion 44 of the bone screw 32 to rotate relative to the housing, while retaining the head 42 of the bone screw within the housing.

[0020] The alignment instrument 22 is also configured to provide radiographic alignment, and as such, the proximal portion of the alignment instrument is increased in diameter relative to the distal portion of the alignment instrument to house a radiographic marker generally depicted by reference numeral 46. In one embodiment, the radiographic marker 46 includes a pair of rings 48, 50. The ring 48 is positioned within the proximal portion of the alignment instrument 22 and, accordingly, has a diameter corresponding to fit within the diameter of the proximal portion. The ring 50 is positioned within the distal portion of the alignment instrument 20 and, accordingly, has a diameter corresponding to fit within the diameter of the distal portion. As such, the rings 48, 50 cooperate to aid with alignment as will be described. It is understood that the rings 48, 50 may be formed of any radiographic

material such as metal. It is further understood that the rings 48, 50 may be replaced with alternative radiographic markers such as metal rods configured to form an X-like shape, thereby also aiding in alignment.

[0021] Referring again to Fig. 2, a pair of clamp assemblies 52, 54 are provided to operatively connect the alignment instrument 22 with the associated implantation device 24. In one embodiment, the implantation device 24 is substantially similar to the instrument described in U.S. Patent Application Serial No. 10/430,473, which is herein incorporated by reference for all legitimate purposes. The inner clamp assembly 52 (relative to the alignment instrument 22) is adapted to slidably engage the alignment instrument 22, and as such, includes a groove 56 defined through an adjustable clamping portion 57 to facilitate the slidable engagement. The inner clamp assembly 52 includes a connector 58, which is adapted to releasably secure the inner clamp assembly 52 to the alignment instrument 22. In the present example, the connector 58 is threaded through the inner clamp assembly 52 to contact the clamping portion 57, and thus can be actuated to engage or disengage the clamping portion with the alignment instrument 22. Accordingly, the inner clamp assembly 52 is adjustable along the X-axis defined by the alignment instrument 22, yet can be secured to the alignment instrument upon adjustment of the inner clamp assembly 52 to a desired position.

[0022] The outer clamp assembly 54 (relative to the alignment instrument 22) is adapted to slidably engage the inner clamp assembly 52. In one embodiment, the outer clamp assembly 54 includes a groove 60 defined therein for allowing the outer clamp assembly to slidably engage the inner clamp assembly 52 via a flange portion 62 of the inner clamp assembly. Accordingly, the outer clamp assembly 54 is adjustable relative to the inner clamp assembly 52 along a Y-axis. For example, in the embodiment of Fig. 2, the outer clamp assembly 54 is laterally adjustable relative to the alignment instrument 22. The outer clamp assembly 54 further includes a connector 64, which is adapted to releasably secure the outer clamp assembly 54 to the inner clamp assembly 52. In the present example, the connector 64 is threaded through the outer clamp assembly 54, and thus can be actuated to engage or disengage with the inner clamp assembly 52.

[0023] As can be appreciated, the inner clamp assembly 52 is rotatable about the alignment instrument 22. Therefore, although described as being a lateral axis as viewed in Fig. 2, descriptions of the Y-axis can change depending on the position of the inner clamp assembly 52 relative to the alignment instrument 22. For example, the inner clamp assembly

52 can be rotated to position the implantation device 24 in the same horizontal plane as the alignment instrument 22. In this example, the outer clamp assembly 54 is still adjustable along the Y-axis, but the Y-axis would be considered an elevational axis.

[0024] The outer clamp assembly 54 is further adapted to receive the implantation device 24 (Fig. 4) via a pair of grooves 66, 68 formed in a pair of corresponding clamping portions 70, 72, respectively, of the outer clamp assembly. The implantation device 24 is adapted for placement within the grooves 66, 68 such that the implantation device is slidable relative to the outer clamp assembly 54. Moreover, an additional connector 74 is associated with the outer clamp assembly 54 to advance the clamping portion 70 towards the clamping portion 72, thereby securing the implantation device 24 within the outer clamp assembly 52 upon adjustment of the implantation device to a desired position. In the present example, the connector 74 is adjustable along a threaded rod (not shown) associated with the clamping portion 70, and thus, the clamping portion 70 can be actuated towards the clamping portion 72 via adjustment of the connector 74. As such, the implantation device 24 is adjustable along an A-axis defined by the longitudinal axis of the implantation device. Of course, the implantation device 24 can be rotated within the outer clamp assembly 54 to adjust to correspond to different positions of the outer clamp assembly relative to the inner clamp assembly 52, and as such, the implantation device is rotatable about the A-axis.

[0025] Referring to Fig. 4, in one embodiment, the bone screw 32 is adapted to be inserted into the vertebrae V1 to provide an anchor point from which to align the associated implantation device 24 prior to insertion of a prosthetic device, generally depicted by reference numeral 80, into the intervertebral space S. Of course, the bone screw 32 may alternatively be inserted into the vertebrae V2. A fluoroscopic machine, or C-arm 82, is further provided to fluoroscopically aid in positioning of the alignment instrument 22. For sake of clarity, the method for aligning the alignment instrument 22 for insertion of the prosthetic device 80 will be described with respect to the anterior/oblique approach to the intervertebral space S; however, it is understood that the alignment process, in a general sense, is adaptable for other approaches to the interverterbral space including the lateral approach.

[0026] In operation, and with continued reference to Fig. 4, the alignment instrument 22 is aligned with fluoroscopic assistance by positioning the C-arm 82 in a direct anterior view of the vertebrae V1, V2 for corresponding to an anterior/oblique insertion approach. The alignment instrument 22 is then positioned such that the bone screw 32 engages the upper

vertebra V1. In one embodiment, the bone screw 32 is positioned relatively close to a midline of the upper vertebra V1, however, it is understood that the exact position of the bone screw relative to the upper vertebra is not critical. Upon proper positioning, the plunger member 26 (Figs. 3A, 3B) is driven against the bone screw 32 to drive the bone screw into the upper vertebra V1, thereby providing a fixed anchor location defined by the position of the bone screw.

[0027] The proximal portion of the alignment instrument 22 is then adjusted to align the radiographic marker 46 with the spherical head 42 of the bone screw 32 as viewed on a monitor (not shown) associated with the C-arm 82. Upon proper alignment determined by viewing the monitor, the alignment instrument 22 is then locked into place by further advancement of the plunger member 26 against the bone screw 32. The implantation device 24 is then placed within the grooves 66, 68 of the outer clamp assembly 54. The position of the implantation device 24 is then adjusted to correspond to the center of the intervertebral space S, and upon reaching the desired position, the position of the implantation device is locked by engaging the connector 64 against the inner clamp assembly 52.

[0028] The implantation device 24 is further adjustable along the A-axis to properly position the prosthetic device 80 for implantation into the intervertebral space S. In one embodiment, proper positioning entails positioning the prosthetic device 80 proximate to the vertebral bodies V1, V2 to the point of touching. Upon proper positioning, the implantation device 24 is locked along the A-axis by engaging the connector 74 against the outer clamp assembly 54. The implantation device 24 is then actuated to insert the prosthetic device 80 into the intervertebral space S.

[0029] Thus, the above-described process and associated instrumentation allows for alignment and implantation of the prosthetic device 80 with minimal fluoroscopic guidance.

[0030] Referring now to Fig. 5, in an alternative embodiment, alignment and insertion of the prosthetic device 80 can be accomplished without fluoroscopic guidance through the use of an alternative alignment instrument 90. The alignment instrument 90 includes a bubble level device 92, which in one embodiment, eliminates the need for radiographic markers and a C-arm fluoroscopic machine. The alignment instrument 90 is substantially similar to the alignment instrument 22 except for the features described below, and, as such, features of the alignment instrument 90 that are substantially similar to features of the alignment instrument 22 are given the same reference numerals.

[0031] The alignment instrument 90 includes a substantially uniform housing 94 through which the plunger member 26 is adapted to move through to engage the bone screw 32. The alignment instrument 90 is adapted for use with the bubble level 92, which may connect with the alignment instrument 90 in any conventional manner, such as via a threaded connection. For example, the bubble level 92 may include a threaded connector 96 for engaging a threaded receptacle 98 defined in the alignment instrument 90. Of course, in some embodiments, the bubble level 92 may be integrally formed with the alignment instrument 90. The bubble level 92 is conventional in most respects, and therefore, includes a cavity (not shown) defined therethrough for holding fluid, and a transparent portion 100 for viewing the fluid.

[0032] In operation, the alignment instrument 90 is used in conjunction with the inner and outer clamp assemblies 52, 54 to align the prosthetic device 80 for insertion into the intervertebral space S. Prior to anchoring of the alignment instrument 90, the patient (not shown) is first aligned at a substantially 90° angle relative to the operating table (not shown). Upon proper alignment of the patient, the bone screw 32 of the alignment instrument 90 is then inserted into the upper vertebra V1 to provide an anchoring point. The proximal, or free, end of the alignment instrument 90 is then aligned to the proper position by adjusting the alignment instrument 90 until the bubble level 92 reflects a neutral position.

[0033] The present disclosure has been described relative to several preferred embodiments. Improvements or modifications that become apparent to persons of ordinary skill in the art after reading this disclosure are deemed within the spirit and scope of the application. For example, during the alignment process, a probe may be used in conjunction with the alignment instrument 22, 90 prior to placement of the implantation device 24. In this manner, proper alignment of the various instrumentation relative to the intervertebral space S may be further ensured. Moreover, although described with reference to an anterior-oblique approach, it is understood that the above-described methods and instrumentation may be used with a variety of insertion approaches. Still further, although the anchoring device is described as a bone screw, a variety of anchoring devices may be used with the alignment instruments 22, 90.

[0034] Accordingly, it is understood that several modifications, changes and substitutions are intended in the foregoing disclosure and, in some instances, some features of the disclosure will be employed without a corresponding use of other features. It is also understood that all spatial references, such as "inner," "outer," "proximal," and "distal" are

for illustrative purposes only and can be varied within the scope of the disclosure. Accordingly, it is appropriate that the appended claims be construed broadly and in a manner consistent with the scope of the disclosure.